

REMARKS/ARGUMENTS

The examiner has rejected claims 1-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In rejecting the claims the examiner points out various instances of alleged indefiniteness in claims 1, 7, 9, 12, 13, 17, 18, 19, 20 and 21. In response to this rejection applicant has amended the claims. Applicant submits that the amended claims are now in full compliance with 35 U.S.C. § 112, for the reasons discussed below.

The examiner urges that the phrase “preferably between 90 and 250 g/m²” in claim 1 is vague and indefinite because it improperly presents a range within a previously recited range. Applicant has therefore deleted this limitation from claim 1 and has added new claim 24 to claim the narrower embodiment embraced by the above-quoted limitation.

The examiner urges that claim 7 is vague and indefinite because it recites the limitation of “rubber” within the previously recited “adhesive”. Accordingly, applicant has deleted the limitation “particularly natural rubber” from claim 7 and has added new claim 25 to claim the embodiment of the invention which requires this particular limitation. With respect to the claimed natural rubber as the adhesive, applicant wishes to point out that natural rubber is obtained from the sap of rubber trees. The sap obtained from the rubber trees is a naturally occurring latex material which is inherently sticky and cohesive and thus is useful as an adhesive material.

The examiner has applied the indefiniteness rejection to claim 9 because this claim presents a range within a range. Accordingly, the limitation of the

narrower range presented in claim 9 (i.e., between 5 and 10 g/m²) has been deleted from claim 9 and applicant has added new claim 26 to claim the narrower embodiment of the invention which uses this particular range.

With respect to claims 12 and 13 the examiner urges that the recitation of "possibly being modified" is vague and indefinite because it is unclear as to what "modifications" are being referred to and whether or not such modifications are required. In response to this portion of the rejection applicant has amended claims 12 and 13 to clarify the indefiniteness noted by the examiner. Claims 12 and 13 presently recite that the cellulose fibers are optionally rayon fibers resulting from sodium hydroxide treatment of viscose or regenerated cellulose fibers in solvent medium. The amended portion of claims 12 and 13 is supported on page 10, lines 32-38.

With respect to the rejection of claim 17 under 35 U.S.C. § 112, second paragraph, the examiner alleges that this claim is vague and indefinite because of the improper dependency recited at the end of the claim. In addition the examiner alleges that claim 17 is also indefinite because the claim refers to a cohesion agent, but in the previous claims rubber has been recited. In response to this portion of the rejection applicant has amended claim 17 so that it no longer improperly depends from claims 4-8. In this regard it is to be noted that claim 17 (prior to the present amendment) recites that the cohesion agent is the adhesive recited in claims 4-8. Claim 17 has been amended so that the cohesion agent is indicated by recitation of a Markush group wherein the members of the Markush group correspond to the adhesives identified in claims 4-8. With respect to the examiner's comments regarding the cohesion agent and its relationship to rubber (i.e., natural rubber) applicant wishes to remind the examiner that natural rubber is obtained from the sap of rubber trees in the form of latex which is naturally

sticky and inherently has adhesive and cohesion characteristics.

The examiner notes that claims 18 and 21 are vague and indefinite because it is unclear what the reference to "it" means. Applicant submits that it is clear in claim 18 that "it" refers to "material" and "it" in claim 21 refers to the "package". Accordingly, applicant has amended claims 18 and 21 so that the claims presently recite that which was absolutely clear or at least implicit in claims 18 and 21.

The examiner urges that claim 19 is vague and indefinite because it merely recites that which has already been claimed (i.e., it does not include any further limitations of the claim from which it depends). Applicant submits that claim 19 claims a package whereas claim 1 from which it depends claims the material which is useful for making such packages. Thus, the difference between claim 19 and claim 1 is self-evident. In other words, claim 19, being directed toward a package, clearly implies that the material from which the package is made must be configured as a package. Applicant has therefore amended claim 19 to include the limitation which is clear or at least implicit from the original language of the claim.

With respect to claim 20, applicant has amended this claim so that it now depends from claim 11 instead of from claim 19.

In view of the above comments and amendments to the claims, applicant submits that claims 1-23 are now in full compliance with 35 U.S.C. § 112, second paragraph.

The examiner has rejected claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over any one of Anthony et al., Shimoyamada et al., Markle et al. or Anderson et al. In rejecting the claims the examiner alleges that each of the cited references teach the known and expected formation of sterilization bags and rigid containers with material formed from cellulose fibers and synthetic fibers adhered in varying arrays of bonding and that such material has bacterial filtration efficiency. The examiner acknowledges that the references are silent with the specific standard strengths of the material. However, the examiner urges that such standards are well recognized as conventional in the art and in fact are referred to by Markle et al. in column 1, lines 30-40. The examiner concludes that it would be well within the purview of one having ordinary skill in the art to form and configure the materials of the cited references so as to optimize the strength and bacterial efficiency thereof.

Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

Before discussing the rejection, applicant first wishes to point out that prior to applicant's invention, no one has been able to solve the problems of the prior art materials and packages as noted on pages 1-4 and the top of page 5 of applicant's specification. In view of a long felt need to solve these problems, applicant set out to develop a sterilizing packaging sheet which has **simultaneously** and necessarily **several** properties (see page 5, lines 10-12). These properties which must be simultaneously obtained in the packaging material include tear resistance, burst resistance, impact strength, sealability, and the material must serve as a barrier to bacteria or other microorganisms. These required characteristics are set forth on pages 9-7 of applicant's specification.

It is noted on page 7 of applicant's specification that it is possible to combine some of the aforementioned characteristics in a single sheet by increasing the grammage of the sheet (see page 7, lines 11-14). Moreover, attempts to import some characteristics are only achieved by diminishing some of the other desired characteristics. In this regard it is noted on page 7, lines 15-20 that if it is attempted to reinforce the surface of the sheets, in order to have greater cohesion for example, by impregnating it with a reinforcing product, its structure is opened up and its bacterial filtering efficiency is reduced.

Applicant has characterized this unique problem in the paragraph which begins on page 7, line 22. In this paragraph it is noted that the problem which must be overcome is to provide a sterilizing packaging sheet which has the above-mentioned required properties, in particular which has both a very high overall mechanical strength and a high microbial barrier characteristic. **In particular, the problem is to provide these characteristics while minimizing the grammage of the material.**

While it might be a straightforward task to provide a packaging sheet material which combines the aforementioned characteristics, it is by no means a simple task nor is it obvious over the prior art to combine these characteristics in a product which has the grammage limitations of applicant's invention. In this regard applicant states on page 7, lines 28-35 that:

The applicant has discovered that, by irreversibly bonding two sterilizing packaging sheets together via one of their sides, especially by pasting, a material is obtained which solves the problem since it has all the desired properties and, in addition, the said material is

in every way superior to a simple sterilizing packaging sheet having the same grammage as the said material.

Turning now to the rejection, applicant submits that none of the cited references recognize the problems associated with combining the aforementioned features in a material for making sterilizing packaging and furthermore, none of these references, either alone or in combination with one another, even remotely disclose or suggest any way of combining these features while maintaining the grammage of the sheet within the grammage limitations recited in applicant's claims.

The examiner urges that it would be well within the purview of one of ordinary skill in the art to form and configure the materials of the cited references so as to optimize the strength and bacterial efficiency thereof. However, the examiner has failed to make any finding of fact that the required characteristics of applicant's invention can be combined in a single packaging material while minimizing an increase in the grammage of the material. This is not surprising in view of the highly competitive field of technology to which the present invention pertains and the failure of others to solve this problem in the manner that applicant has solved it. Furthermore, applicant wishes to remind the examiner that the mere fact that references can be modified is not sufficient to establish *prima facie* obviousness. In this regard the examiner's attention is directed to MPEP § 2143.01 which states in part:

A statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the claimed invention was made' " because the references relied upon teach that all aspects of

the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.

It is also to be noted from MPEP § 2143.02 that there must be reasonable expectation of success for the modified prior art. It is clear from the above-described difficulties in combining the aforementioned characteristics without creating an unacceptable increase in grammage, that there is no reasonable expectation of success apparent in the prior art. In fact, just the opposite is expected in view of the long felt need to create such a product and the failure of others to do so.

In addition to the above, applicant also submits that the references cited by the examiner do not disclose or suggest applicant's invention for the reasons discussed below.

Anthony et al. disclose a storage system of a material having two sheets, the sheets being not sealed at the same time during the sterilization process. The two sheets may be joined at their periphery but they comprise an unjoined peripheral portion in order to allow the two step sterilization procedure. This unjoined portion is necessary to allow penetration of the sterilizing gas which means that the sterilizing material does not allow the penetration of the gas. In contrast, according to applicant's invention, the sterilizing material is made of two sheets which are joined uniformly and without an unjoined portion because the material permits penetration of the sterilizing gas. Consequently, the material of applicant's invention is advantageous since it does not require a two step sterilization procedure.

The material of applicant's invention and the material described by Anthony et al. clearly do not have the same properties regarding the penetration of sterilizing gas. It is therefore self-evident that these materials have different physical characteristics. Thus, it is clear that applicant's invention is new and unobvious over Anthony et al.

Markle et al. disclose a package having a cover made of a thin sheet of extruded coated paper, a layer of polyethylene and a heat sealable lacquer. The layer of polyethylene is not a sterilizing sheet and is continuously joined to the "paper" which is a Tyvek synthetic "paper". Markle et al. are silent about the characteristics of this thin sheet.

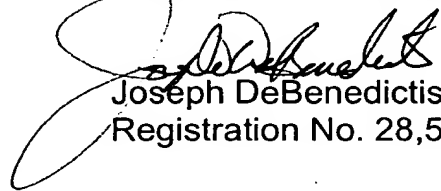
Anderson et al. disclose a packaging having a spunbonded olefin sheet deformed for making a pocket containing the medical device to be sterilized. The open part is sealed with a lidding sheet with microbial resistant characteristics. Anderson et al. do not disclose a sterilizing material comprised of joined sheets as required by applicant's invention. Furthermore, according to the invention of Anderson et al., there is no pocket between the joined sheets for placing the medical device to be sterilized. Instead, the device is placed on the material, not between the sheets. Moreover Anderson et al. are silent about the characteristics of their thin sheet.

U.S. Pat. Appl. 09/555,525

In view of the above arguments and amendments to the claims, applicant respectfully requests reconsideration and allowance of all the claims which are currently pending in the application.

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Respectfully submitted,



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